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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,263	10/31/2000	Anthony J. Cutie	540541-2013.1	1107

20999 7590 05/30/2002

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EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/702,263

Applicant(s)

CUTIE ET AL.

Examiner

Robert M DeWitty

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

Claims 1-17 are pending in the instant application. Acknowledgement of Applicant's response filed 4/4/02 is acknowledged.

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitcomb (U.S. Pat. No. 6,011,049).

Whitcomb teaches the use of pioglitazone plus metformin together in a single formulation, such as a tablet or capsule (col. 4, lines 31-37). These combinations produce better than expected control of non-insulin dependent diabetes mellitus (col. 5, lines 2-6).

Whereas Whitcomb does not teach a first layer and a core covered by at least a portion of the first, it is understood by the examiner that in the combination of pioglitazone and metformin, portions of pioglitazone would cover metformin.

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2. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieveley (U.S. Pat. No. 6,153,632).

Rieveley teaches the treatment of diabetes mellitus by combining an insulin

sensitizer with the insulin, thereby enabling cells of the body to function with lower levels of the insulin (col. 5, lines 52-67). A list of suitable insulin sensitizers includes pioglitazone HCl. The insulin can be a biguanide, such as Metformin or Glucophage.

Rieveley does not explicitly state the use of pioglitazone HCl in the first layer and core, but it is understood by the examiner that in a combination of pioglitazone and metformin, portions of pioglitazone would cover metformin.

### ***Response to Arguments***

3. Applicant's arguments filed 4/4/02 have been fully considered but they are not persuasive.

Applicant asserts that it is mere conjunction on the part of the examiner that one with ordinary skill in the art would know that in a tablet, portions of metformin would be covered by pioglitazone. However, in the instant specification, Applicant states it is understood that the first layer and/or the core layer of the formulation could contain a mixture of the two ingredients depending on the rate of administration to the patient (page 3, second full paragraph). In both prior art teachings (Whitcomb and Rieveley), pioglitazone and metformin are mixed together in the formulation. Therefore, the outside layer of the formulation would contain samples of both, and the interior would contain samples of both. As such, portions of metformin in the interior would be covered by pioglitazone on the exterior. Therefore, the instant invention would have been obvious to one with ordinary skill in the art.

Thus, the rejections are maintained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

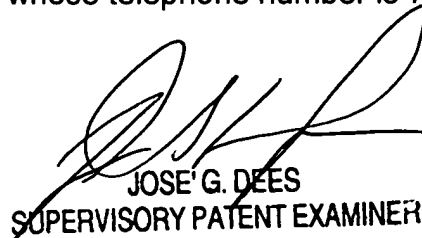
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
5/28/02

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

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